REMARKS

SUMMARY OF AMENDMENTS

Claims 2 and 19-55 have been withdrawn. Claims 1 and 3-18 are pending and currently being examined in this application.

35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1 and 3-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states that the claims contain subject matter not described in the specification in such a way as to convey to one skilled in the art that the inventor had possession of the invention at the time the application was filed. This rejection is respectfully traversed.

In contrast to *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, cited by the Office Action, the present Specification does provide a working example of a probe according to claim 1 and does not merely present a wish. According to M.P.E.P. § 2163, an applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d at 956, 964 (Fed. Cir. 2002). The present Specification provides such sufficiently detailed, relevant identifying characteristics by disclosing a complete structure of an exemplary probe in accordance with the claimed invention. Thus, the Applicant has demonstrated actual possession of the claimed invention as of the priority date.

As recognized by the Examiner, the present specification provides a working example of the invention and a general method for preparing and isolating aptamers capable of binding a selected target. Office Action at 3. The Specification further notes that aptamers capable of binding various compounds, such as theophylline, FMN, AMP, arginine, citrulline, tobramycin, and neomycin B have also been isolated and characterized. Specification at 13 (citing Hermann and Patel, *Science*, 287, 820-825 (2000)). Further, at the time the application was filed, those of skill in the art would have been familiar with the ability of other molecules, such as nucleic acid molecules, among others, to specifically bind to particular targets with particular affinities.

In addition to providing a working example of an allosteric probe, the Specification provides detailed guidance for a method of developing an allosteric probe. The method is described using an LPS aptamer as the regulator and an ATP aptamer as the regulated aptamer. One of skill in the art, however, would understand that the principles provided by the present specification are more broadly applicable. For example, the Specification notes that when designing an allosteric probe according to an embodiment, it is preferable to choose aptamers with affinities at least a log unit apart with the regulated aptamer having the lower affinity. Specification at 25. The Specification further provides a method for isolating probes having the desired allosteric characteristics. Specification at 25-26. Those of skill in the art at the time the invention was made would recognize that the method is generally applicable to the development and isolation of allosteric probes. Moreover, the Specification provides specific guidance regarding the selection, development, and isolation of allosteric probes in accordance with the claimed invention.

In connection with the prophetic example of an allosteric CLAMP, the Specification illustrates another example of a probe design and method for forming and

selecting probes that meet a desired design within the scope of the claimed invention. The prophetic example specifically illustrates how an intended use for a probe provides guidance for the probe's design. Specification at 27-33. Again, one skilled in the art at the time the invention was made would readily appreciate that the principles illustrated by the prophetic example are more generally applicable.

Based on the present Specification, one skilled in the art at the time the invention was made would recognize that Applicant was in possession of the invention of claim 1 at the time the application was filed. Claim 1 clearly recites a probe comprising an allosteric regulator and a regulated aptamer, each of which are readily identifiable by one of ordinary skill in the art based on the guidance provided by the present specification. Claim 1 further recites that "the binding the allosteric regulator with a first target enhances the binding of the at least one regulated aptamer to at least one second target." The Specification provides examples of and guidance for selecting an appropriate allosteric regulator and regulated aptamer; and further provides examples of and guidance for selecting a probe having the characteristic recited in claim 1.

For at least these reasons, the specification provides sufficient direction to make and use the claimed invention without undue experimentation. Therefore, the rejection under 35 U.S.C. § 112 should be withdrawn.

35 U.S.C. § 102(b)

Claims 1, 3, 4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Soukup et al. Applicant respectfully traverses the rejection.

Soukup et al. relates to allosteric ribozymes. Allosteric ribozymes regulate the rate of a reaction catalyzed by the ribozyme portion of the molecule. For example, a reaction catalyzed by a ribozyme can be represented as A+ B ⇔ AB ⇨ A + C. The regulatory portion of the allosteric ribozyme (i.e., antisense molecule, small molecule binding molecule) regulates the second step of this reaction (e.g., AB ⇨ A + C) rather than the first step of the reaction (A+ B ⇔ AB). Thus, allosteric ribozymes are not designed to overcome the energy barriers to the transition between certain conformational states. In other words, the allosteric ribozyme does not drive the formation of AB from A + B. Rather, allosteric ribozymes increase the rate of the catalysis of AB into A + C. See Soukup et al. at 469 (noting that ligand binding to the allosteric site of an allosteric ribozyme enhances or inhibits catalytic activity).

In contrast, claim 1 recites that "binding the allosteric regulator with a first target enhances the binding of the at least one regulated aptamer to at least one second target." The term "enhanced binding" refers to an increased strength in the attraction or associations of one molecule to another molecule as measured, for example, by the dissociation constant, K_d, which is a measure of the relative concentrations of the components AB ↔ A + B at equilibrium. Specification at 10. A small K_d indicates stronger or more enhanced binding between two molecules (e.g., A and B). Soukup et al. fail to teach or even suggest that binding the allosteric regulator with a first target enhances binding of the at least one regulated aptamer to at least one second target"

and thus fails to teach or suggest all of the elements of the claims. For at least these reasons, the rejection of claims 1, 3, 4 and 6-7 under 35 U.S.C. § 102(b) should be withdrawn.

35 U.S.C. § 102(b)

Claims 1, 3, 4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chinnapen et al. Applicant respectfully traverses the rejection.

Chinnapen et al. relate to DNA aptamers that are able to simultaneously bind cytochrome c and hemin. Specifically, in Chinnapen et al., the binding of hemin to the DNA aptamer stimulates the binding of cytochrome c to the same aptamer. Thus, Chinnapen et al. does not disclose or suggest "an allosteric regulator linked to at least one regulated aptamer," as recited by claim 1. Rather, Chinnapen et al. discloses a single aptamer and thus fails to teach or suggest all of the elements of the claims. For at least these reasons, this rejection should be withdrawn.

35 U.S.C. § 102(a)

Claims 1, 3, 4 and 6-7 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Burke et al. Applicant respectfully traverses the rejection.

Burke was published on April 24, 2002. The subject matter of the claimed invention was conceived of and reduced to practice prior to this date. A Rule 131 Declaration, signed by the inventor of the present application attesting to the prior conception and reduction to practice is attached. The Declaration establishes a "prior invention" by showing that the inventor reduced the invention to practice prior to the effective date of the Burke et al. reference (i.e., April 24, 2002). *See* M.P.E.P. § 715.07. A Rule 131 Declaration can be used to "antedate a reference or activity that qualifies as

prior art under 35 U.S.C. 102(a) . . . where the prior art date under 35 U.S.C. 102(a) of the patent, the publication or activity used to reject the claim(s) is less than 1 year prior to applicant's or patent owner's effective filing date." M.P.E.P § 715. Accordingly, Burke et al. is not a proper reference and all and withdrawal of this rejection is respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner should believe that anything further may be required to place this application in even better form for allowance, he is cordially invited to telephone the undersigned attorneys for Applicant.

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Respectfully submitted,

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